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<b>O.I.P.E. TRANSMITTAL FORM</b> JAN 29 2007 PATENT OFFICE	Application Number	10/568,941
	Filing Date	February 21, 2006
	First Named Inventor	Michael Horstmann et al.
	Art Unit	1614
	Examiner Name	
Total Number of Pages in This Submission		Attorney Docket Number R04150US (#90568)

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
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<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	Please charge any additional fees or credit any overpayment to Deposit Account No. 08-2441.	

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	D. Peter Hochberg Co., L.P.A.		
Signature			
Printed name	D. Peter Hochberg		
Date	January 26, 2007	Reg. No.	24,603

## CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

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Typed or printed name	Christine Kotran	Date	1/26/2007

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Michael Horstmann et al.  
Serial No.: 10/568,941  
Filed: February 21, 2006 / Conf. No. 7611  
Title: TRANSDERMAL PHARMACEUTICAL PREPARATION  
CONTAINING ACTIVE SUBSTANCE COMBINATIONS  
FOR TREATING PARKINSON'S, DISEASE  
Examiner: \_\_\_\_\_ / Art Unit: 1614  
Attorney File: RO4150US (#90568)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL FOR POWER OF ATTORNEY AND  
INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

Sir:

Enclosed for entry on the records of the USPTO are a Power of Attorney duly executed by the inventors and an English translation of the International Preliminary Report on Patentability rendered on the parent International Application No. PCT/EP2004/009136. The IPRP was transmitted to the designated/elected Offices on July 20, 2006.

Respectfully submitted,

By: \_\_\_\_\_

D. Peter Hochberg  
Reg. No. 24,603

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Christine Kotran: \_\_\_\_\_

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1/26/2007

From the INTERNATIONAL BUREAU

**PCT**

NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY  
(CHAPTER I OR CHAPTER II  
OF THE PATENT COOPERATION TREATY)  
(PCT Rules 44bis.3(c) and 72.2)

To:

FLACCUS, Rolf-Dieter  
Bussardweg 10  
50389 Wesseling  
ALLEMAGNE

**Eingegangen**

26. JULI 2006

FRIST:.....

Date of mailing (day/month/year)  
20 July 2006 (20.07.2006)

Applicant's or agent's file reference  
LTS 2003/005 PCT

**IMPORTANT NOTIFICATION**

International application No.  
PCT/EP2004/009136

International filing date (day/month/year)  
14 August 2004 (14.08.2004)

Applicant

LTS LOHMANN THERAPIE-SYSTEME AG et al

**1. Transmittal of the translation to the applicant.**

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

**2. Transmittal of the copy of the translation to the designated or elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

KR

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

**3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Authorized officer

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**Translation**

**PATENT COOPERATION TREATY**

**PCT**

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>LTS 2003/005 PCT</b>	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. <b>PCT/EP2004/009136</b>	International filing date (day/month/year) <b>14.08.2004</b>	Priority date (day/month/year) <b>20.08.2003</b>
International Patent Classification (IPC) or national classification and IPC <b>A61K9/70</b>		
Applicant <b>LTS LOHMANN THERAPIE-SYSTEME AG</b>		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input checked="" type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/009136

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language \_\_\_\_\_ which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-15 \_\_\_\_\_ as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☒ the claims:
- nos. \_\_\_\_\_ as originally filed/furnished
- nos.\* \_\_\_\_\_ as amended (together with any statement) under Article 19
- nos.\* 1-13 \_\_\_\_\_ received by this Authority on 14.06.2005 with letter
- nos.\* \_\_\_\_\_ received by this Authority on of 13.06.2005
- ☐ the drawings:
- sheets \_\_\_\_\_ as originally filed/furnished
- sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (specify): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (specify): \_\_\_\_\_
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (specify): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (specify): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/009136

Box No. II

Priority

1. ☒ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:
  - ☒ copy of the earlier application whose priority has been claimed (Rule 66.7(a)).
  - ☐ translation of the earlier application whose priority has been claimed (Rule 66.7(b)).
2. ☐ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rule 64.1). Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/009136

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

## 1. Statement

Novelty (N)

Claims 1-13

YES

Claims

NO

Inventive step (IS)

Claims

YES

Claims 1-13

NO

Industrial applicability (IA)

Claims 1-13

YES

Claims

NO

## 2. Citations and explanations (Rule 70.7)

**Novelty**

1. Claims 1-13 appear to meet the requirements of PCT Article 33(2) for novelty, since none of the prior art citations discloses the subject matter of these claims (transdermal medicinal preparation containing said combination of active substances).

**Inventive step**

2. The present invention can therefore be considered to address the problem of providing "alternative combination therapies for treating Parkinson's disease".

The solution consists in **transdermal** medicinal preparations.

Transdermal medicinal preparations which contain dopamine agonists are already known from the prior art (cf. D7, D8 and D11).

The subject matter of claims 1 and 2 differs from documents D7, D8 and D11 in that the claimed medicinal preparation contains additional active substances. This **combination of particular active substances in a**

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/009136

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

**transdermal medicinal form** is unknown from the prior art.

These active substances have already been successfully administered transdermally as a combination therapy, but not in the claimed combinations (cf. D2: MAO-B inhibitor and anticholinergic agents; D3: MAO-B inhibitor and dopamine agonist; D4: MAO-B inhibitor and NMDA agonist).

In view of the explanations in the prior art, a person skilled in the art would consider it a conventional procedure to combine a dopamine agonist or L-dopa with other anti-parkinsonian agents, in order to achieve the same effect.

This type of transdermal combination, as defined in the claims, can only be considered inventive if the particular combination of active substances shows unexpected effects or properties in relation to the prior art. **However, the application does not indicate such effects or properties.**

Consequently, the application cannot be recognised to involve an inventive step (PCT Article 33(3)).



INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/009136

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

**PCT Article 19**

The new claim 7 is not allowed because the specific combination of sympathicomimetic agents with the active substances mentioned in the preceding claims was not explicitly disclosed in the original application.